would we do with the submission which we had already provided to the authority in the UK, how to handle that.

Q Reading from the first paragraph of your July 25, 1985 memorandum, quote, as a result of a recent in-use test on Zantac Syrup in which we found there was a significant loss of propylparaben due to microbial contamination, the development program of this syrup has been delayed pending further investigation. End quote. Does that accurately reflect your assessment of the problem?

A Yes, it does.

Q Returning to the time line July 1985, does this memorandum reflect that event depicted on trial exhibit 116?

A I'll have to look at it in the file. I can't quite read that. 116?

Q Yes.

A Could you give me the question again?

Q I jumped ahead. The November 1983 to July 1985 states on trial exhibit 116, quote, further work revealed that, although Glaxo's original ranitidine syrup formulation met the requirements of the Antimicrobial Preservative Effectiveness test of the USP, it supported the growth of a water-borne bacterium known as *Pseudomonas cepacia*. It's referencing trial exhibit 64. Your testimony thus far is coinciding with this event and this memorandum; is that correct?

A That's correct, yes.
Q Dr. Long, did you solve the problem posed by *Pseudomonas cepacia* with respect to the Zantac Syrup?
A Yes. There was a period of intense thinking, speculation, what preservatives could we use, considered a whole range, and then looked, considered all the criteria that we would need to consider in selecting a preservative, an additional preservative. As a result of that ethanol was one of the candidates.
Q What amount of the alcohol did you ultimately settle upon to solve this problem posed by the *Pseudomonas cepacia*?
A We ultimately settled on 7.5 percent weighted body.
Q Did that addition of that amount of alcohol work to solve the problem. Did it eradicate the contamination?
A Yes, it did.
Q I direct your attention to plaintiffs' trial exhibit 245. I note for the Court this is an excerpt of Glaxo's April 1986 amendment to its initial new drug application for Zantac Syrup in the United States. I direct your attention to Y72, Y072400. That's plaintiffs' trial exhibit 245.

Dr. Long, having reviewed this and based on your knowledge, do you confirm in this text Glaxo is advising the Food and Drug Administration of its modified syrup formulation containing the alcohol?
A Yes. This page describes the background and what the

formulations of Zantac Syrup reflected in Table D8.1?
A Yes.
Q Directing your attention to Y060620, could you turn to that page and take a minute to review it, Doctor?
(Pause for document examination.)
A Yes. The crux of this page is that we have predicted a shelf-life of 18 months when stored at 2 to 30 degrees centigrade and that the addition of ethanol does not adversely affect the stability of the ranitidine.
Q Glaxo wasn't claiming any shelf-life extension or stability enhancements of the alcohol-containing formulation at this time?
A At that time, no. I was pleased there was no adverse effect because that is what I was looking for.
Q That was a concern at that point in time, that the addition of alcohol to the syrup formulation might actually impact stability in a negative way; is that correct?
A That's correct. In any formulation, in my experience, if we had an extra ingredient it increases the risk of some sort of interaction. There are already eleven ingredients in the syrup, we have added a twelfth. It's quite an exquisite cocktail potential for interactions.
THE COURT: It had nothing to do with the ethanol itself so much but a general concern over --
THE WITNESS: A general concern just adding another